Method for Solid Tumor Analysis with Saphyr Published by Penn State Institute for Personalized Medicine, Opening Largest Oncology Market to Optical Genome Mapping

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Publication demonstrates that Saphyr can be powerful and easy to use for solid tumor analysis in cancer research and clinical testing

SAN DIEGO, Feb. 11, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), announced the publication of a method for using optical genome mapping (OGM) to identify structural variants (SVs) that drive cancer in a wide variety of solid tumor samples. The study, led by Dr. James Broach, Chair of the Department of Biochemistry and Molecular Biology and Director of the Penn State Institute for Personalized Medicine, used the Saphyr® system for OGM to characterize structural variation in twenty solid tumor samples from cancer patients. The study showed that Bionano's workflow can routinely isolate ultra-high molecular weight DNA from solid tumors, that its software is able to identify the cancer-specific variants in the tumor, even when they are present at low abundance in highly complex tumors, and that in every sample OGM found variants affecting important cancer genes. OGM with Saphyr has been previously validated in constitutional genetic diseases from blood samples and hematologic malignancies from blood and bone marrow aspirates. The current study demonstrates that OGM with Saphyr is also simple to use with solid tumors, the most common sample for cancer research and clinical testing.

Using Bionano's SP Tissue and Tumor DNA Isolation Kit, Dr. Broach's team successfully extracted ultra-high molecular weight DNA from a wide variety of human solid tumors including breast, colon, liver, brain, bladder, kidney, lung, ovary, prostate and thyroid cancer tissue. Every tumor sample carried at least one SV affecting important tumor-suppressor or oncogenes and most contained multiple variants. Several of the genes identified by OGM offer the opportunity for targeted therapies.

Jim Broach, PhD, commented: "Oncologists studying liquid tumors, such as leukemia, have had the ability to visualize somatic SVs across the entire tumor genome through karyotyping. This tool has afforded enormous benefits for prognosis and treatment selection, resulting in significant and steadily improving outcomes for such patients. Solid tumors cannot be analyzed by karyotyping, meaning that oncologists dealing with those tumors - breast, lung, prostate, brain, etc. - have not had that tool in their diagnostic arsenal. Our results with Bionano's OGM technology demonstrate the feasibility not only of obtaining the same global view of somatic SVs across the entire solid tumor genome but also of doing so with a 10,000 times greater resolution than that afforded by karyotyping. We anticipate that, like the recent history with karyotyping and liquid tumors, OGM will yield unprecedented insights into solid tumor diagnosis and treatment with the potential for the same steady increase in improved patient outcomes."

Erik Holmlin, PhD, CEO of Bionano Genomics commented: "The ability of an oncologist to prescribe the optimal treatment for a cancer patient depends on their ability to fully characterize all variants found in the patient's tumor. Studies from around the world had already shown that Saphyr detects SVs comprehensively in a variety of leukemias. Dr. Broach's work now demonstrates that Saphyr is uniquely capable of identifying clinically important SVs in solid tumor samples as well and that it does so with a simple, automated analysis workflow that doesn't require complex bioinformatic analysis. By adding solid tumors analysis to that of leukemias for both cancer research and clinical testing, the largest market in oncology becomes accessible to Bionano."

The publication is available on medRxiv at https://www.medrxiv.org/content/10.1101/2021.02.04.21250683v1

About Bionano Genomics

Bionano is a genome analysis company providing tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing, and providing diagnostic testing for those with autism spectrum disorder (ASD) and other neurodevelopmental disabilities through its Lineagen business. Bionano's Saphyr system is a research use only platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics. The Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools. Bionano provides genome analysis services to provide access to data generated by the Saphyr system for researchers who prefer not to adopt the Saphyr system in their labs. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concerns. For more information, visit www.bionanogenomics.com or www.lineagen.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: Saphyr's capabilities in comparison to and in conjunction with other genome analysis technologies, including in the comprehensive analysis of cancer genomes; the potential for Saphyr to reduce or eliminate sequential and confirmatory assays and expedite patient treatment; our expectations regarding the adoption of Saphyr as a clinical tool to replace traditional standard of care cytogenomic testing methods; and the execution of Bionano's strategy. Each of these forward-looking statements involves risks and uncertainties. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: the impact of the COVID-19 pandemic on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive products; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; the ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; the loss of key members of management and our commercial team; and the risks and uncertainties associated with our business and financial condition in general, including the risks and uncertainties described in our filings with the Securities and Exchange Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2019 and in other filings subsequently

made by us with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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